

Appin. S.N. 10/625,813
Amdt. dated September 23, 2005
Reply to Office Action of July 25, 2005
Docket No. 10008113-4

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REMARKS

Entry of the foregoing amendments to the application is requested on the grounds that the claims, as amended, patentably distinguish over the cited art of record or, alternatively, place the application in better condition for appeal. The claims more particularly point out and distinctly claim the subject matter which Applicant regards as the invention. No new issues have been added which would require further consideration and/or search, nor has any new matter been added. The claims as amended are believed to avoid the rejections applied in the July 25, 2005 Final Office Action for reasons set forth more fully below.

Upon entry of this Communication, claims 12-26, 31 and 32 remain in the application. Reconsideration of the claims as currently set forth is requested.

Claims 12, 19-21 and 31 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting (ODP) as being unpatentable over claim 1 of co-pending Application No. 11/017,163. It is submitted that this ODP rejection (as well as the ODP rejections in the previous Office Action) is erroneously placed, in that 11/017,163, filed December 20, 2004, was filed later than the instant application. Further, Applicant is filing concurrently herewith a Petition to Withdraw a Recorded Terminal Disclaimer Pursuant to 37 C.F.R. 1.182 and MPEP 1490. In this Petition, Applicant is withdrawing the three previously filed terminal disclaimers, as each of the three respective pending applications were filed later than the effective filing date of the instant application.

As such, it is respectfully requested that the ODP rejections over each of the four later filed applications be withdrawn.

Claims 12, 13, 16, 19-25, 31 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Wirch (US 5,881,716). The Examiner states that Wirch discloses an apparatus for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium. He asserts that the apparatus of Wirch includes a reservoir capable of containing one fluid pharmaceutical component, a fluid drop generator (item 8) fluidically coupled to the reservoir (item 5); and a control (columns 2-3) activating the fluid drop

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generator to eject a variably selected quantity of the pharmaceutical component onto the medium. The Examiner further asserts that, with regard to claim 22, the control unit of Wirch "is capable of storing the identity of the pharmaceutical component."

Applicant respectfully submits that Wirch does not teach or suggest a fluid drop generator configured to eject/dispense a pharmaceutical component "onto a pharmaceutical dosage form" as recited in Applicant's claims 12 and 20. In sharp contrast, Wirch teaches a dosing device suitable for use in inhalators or infusion instruments. Such devices are configured to dispense liquids directly into a living being, as opposed to being configured to eject/dispense a pharmaceutical component "onto a pharmaceutical dosage form" as recited by the Applicant.

As to claim 22, it is respectfully submitted that the Examiner's assertion that the control unit of Wirch "is capable of storing the identity of the pharmaceutical component" is totally without support or suggestion from Wirch itself. Wirch describes his control unit 22 in terms of controlling the dosage amount of the inhaler/infusion device; and Wirch offers no motivation as to why one skilled in the art would want to have the control unit identify the pharmaceutical component. As such, it is submitted that the Examiner's rejection of claim 22 over Wirch is erroneously based.

For the above reasons, it is submitted that Applicant's invention as defined in claims 12, 20 and in those claims depending ultimately therefrom is not anticipated, taught or rendered obvious by Wirch, either alone or in combination, and patentably defines over the art of record.

Claims 12-15, 18-26, 31 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Voges (US 5,894,841). The Examiner asserts that Voges discloses an apparatus for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir capable of containing one fluid pharmaceutical component, a fluid drop generator (item 14) fluidically coupled to the reservoir (item 10); and a control (item 16) activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium. The Examiner also states that the exact dose amount can be selected by an operator.

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Applicant respectfully submits that Voges does not teach or suggest a fluid drop generator configured to eject/dispense a pharmaceutical component "onto a pharmaceutical dosage form" as recited in Applicant's claims 12 and 20. Voges teaches a dispenser "for administering a substance to a human or animal subject..." via inhalation or topical application (see Col. 3, lines 33 et seq.). As such, Voges actually **teaches away** from dispensing the substance onto a pharmaceutical dosage form. In sharp contrast, Applicant's apparatus as recited in claims 12 and 20 is not supplying a liquid to a human or animal, rather it is configured to eject/dispense a pharmaceutical component "onto a pharmaceutical dosage form."

As to claim 22, it is respectfully submitted that the Examiner's assertion that the control unit of Voges "is capable of storing the identity of the pharmaceutical component" is totally without support or suggestion from Voges itself. Voges describes his control means 16 in terms of controlling the dosage amount/dosage frequency of the nicotine dispenser/inhaler; and Voges offers no motivation as to why one skilled in the art would want to have his control means 16 identify the pharmaceutical component. As such, it is submitted that the Examiner's rejection of claim 22 over Voges is erroneously based.

For the above reasons, it is submitted that Applicant's invention as defined in claims 12, 20 and in those claims depending ultimately therefrom is not anticipated, taught or rendered obvious by Voges, either alone or in combination, and patentably defines over the art of record.

Claims 12-13, 17, 19-25, 31 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Moldavsky (US 6,061,608). The Examiner asserts that Moldavsky discloses an apparatus capable of being used for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir (pump 25 in which the liquid 17 is stored) capable of containing one fluid pharmaceutical component, a fluid drop generator (item 23) fluidically coupled to the reservoir; and a control (item 22 and 30) capable of activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium.

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Applicant respectfully submits that Moldavsky does not teach or suggest a fluid drop generator configured to eject/dispense a pharmaceutical component "onto a pharmaceutical dosage form" as recited in Applicant's claims 12 and 20. Moldavsky teaches a dispenser for precisely dispensing a controlled amount of a liquid. However, Moldavsky does not teach a reservoir containing a fluid pharmaceutical component, nor does he teach that the component is ejected onto a pharmaceutical dosage form.

For the above reasons, it is submitted that Applicant's invention as defined in claims 12, 20 and in those claims depending ultimately therefrom is not anticipated, taught or rendered obvious by Moldavsky, either alone or in combination, and patentably defines over the art of record.

Claims 12-13, 19-26, 31 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Burns (US 5,284,133). The Examiner states that Burns discloses an apparatus capable of being used for manufacturing a pharmaceutical dose onto a pharmaceutical receiving medium, the apparatus comprising a reservoir (item 10) capable of containing one fluid pharmaceutical component, a fluid drop generator (nebulizer - recited in column 10, lines 35-51) fluidically coupled to the reservoir; and a control (Figure 2, and see column 9) capable of activating the fluid drop generator to eject a variably selected quantity of the pharmaceutical component onto the medium.

Applicant respectfully submits that Burns teaches an inhalation device for delivering medication to a patient. Such devices dispense liquids directly into a living being, as opposed to teaching or suggesting a fluid drop generator configured to eject/dispense a pharmaceutical component "onto a pharmaceutical dosage form" as recited in Applicant's claims 12 and 20.

For all the reasons stated above, it is submitted that Applicant's invention as defined in claims 12, 20 and in those claims depending ultimately therefrom is not anticipated, taught or rendered obvious by Burns, either alone or in combination, and patentably defines over the art of record.

Claim 15 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Voges (US 5,894,841) as applied to claim 14 above. The Examiner states that Voges

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discloses that the dispenser can be provided with a plurality of cartridges or reservoirs, each of which can hold a different component. Furthermore, the Examiner states that as to claim 15, Voges discloses that the fluid generator can have more than one fluid drop generator. The Examiner admits that Voges fails to teach that the different fluid drop generators are used for the different medications. The Examiner takes "official notice" that it would have been well known and conventional to have linked the multiple drop generators with individual cartridges or reservoirs. Further, the Examiner asserts that one skilled in the art would immediately recognize that connecting the reservoirs to the generators would enable the storage of multiple pharmaceuticals in one device, and multiple dosing regimes, without cross-contamination. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized various generators separately connected to the reservoirs in order to reduce cross-contamination.

Reiterating previous arguments, Applicant respectfully submits that Voges teaches a dispenser "for administering a substance to a human or animal subject..." via inhalation or topical application. Assuming *arguendo* that it would be obvious to connect the reservoirs to the generators, such combination would still not render Applicant's invention as recited in claim 15, as the device rendered would not include a fluid drop generator configured to eject/dispense a pharmaceutical component "onto a pharmaceutical dosage form" as recited in Applicant's claim 12, from which claim 15 ultimately depends. Rather, following the teaching of Voges, the device would be capable of dispensing a solution for inhalation or topical application for a human or animal subject, not configured to eject onto a pharmaceutical dosage form.

As such, Applicant respectfully submits that his invention as defined in claim 15 is not anticipated, taught, or rendered obvious in view of Voges, either alone or in combination, and patentably defines over the art of record.

Claim 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over either of Wirch or Voges as applied to claim 12 above, and further in view of Moldavsky. The Examiner admits that neither Wirch nor Voges discloses a weight detector for

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detecting and outputting signals corresponding to the weight of the pharmaceutical receiving medium after the one pharmaceutical component has been dispensed onto the pharmaceutical receiving medium. The Examiner states that Moldavsky discloses a weight detector (item 21) for detecting and outputting signals corresponding to the weight of the pharmaceutical receiving medium after the one pharmaceutical component has been dispensed onto the pharmaceutical receiving medium (Applicant notes that, contrary to the assertion by the Examiner, **nowhere** does Moldavsky disclose or even suggest ejecting a pharmaceutical component onto a pharmaceutical dosage form; in fact, Moldavsky teaches a liquid (e.g. epoxy) dispenser for applying liquid to manufactured components such as "printed wiring board[s]"). Further, the Examiner states that Moldavsky discloses that such weight control allows for improvements in the volumetric accuracy and repeatability of the dispensing process (see column 1, lines 59-62). The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized such weight controls in the inventions of Wirch or Voges in order to achieve volumetric accuracy and repeatability.

Applicant again respectfully submits that none of the cited references disclose ejecting a pharmaceutical component onto a pharmaceutical dosage form. As such, the combination of the above-cited references would not render Applicant's invention as recited in claim 17.

Still further, it is submitted that the skilled artisan would not be led to combine Wirch and Voges, which teach dispensing into or onto a human being with Moldavsky, which teaches a machine for dispensing liquids, such as epoxies, onto manufactured articles such as printed wiring boards. It is submitted that there is no motivation for such combination, as the skilled artisan would not see any need for weighing a person/animal (the Examiner apparently is equating a live being with a pharmaceutical medium) to whom the pharmaceutical is being delivered via the inhaler/infusion device of the Wirch and Voges patents.

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For all the reasons stated above, it is submitted that Applicant's invention as defined in claim 17 is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

In response to Applicant's arguments, the Examiner asserts that any substrate which receives a pharmaceutical is inherently a pharmaceutical receiving medium. Further, the Examiner states that, assuming the substrates of the references were excluded, a recitation of intended use must result in a structural difference between the claimed invention and the prior art. He states that the pharmaceutical receiving medium is not part of the apparatus, and thus that the apparatus does not distinguish from the prior art.

Applicant has revised claims 12 and 20 to recite that the pharmaceutical is ejected/dispensed on a pharmaceutical dosage form (this had been previously recited in claims 31 and 32). It is submitted that a living being/printed wiring board is/are NOT inherently a pharmaceutical dosage form.

Further, it is submitted that there is a structural difference between Applicant's manufacturing apparatus/replaceable cartridge and the prior art. The apparatuses of the prior art do not teach or suggest a fluid drop generator configured to eject/dispense a quantity of a pharmaceutical component onto a pharmaceutical dosage form. It is submitted that the prior art's dispensing mechanisms are configured to dispense into/onto their stated substrates, thus resulting in a structural configuration difference between the cited apparatuses and that of Applicant's invention as recited in claims 12 and 20.

Claim 12 has been amended to recite "at least one" pharmaceutical component. Support for this revision may be found in the specification as filed, at least in claim 20 as filed (and as currently pending). Claims 31 and 32 have been revised to recite that the dosage form is ingestible. Support for this revision may be found in the specification as filed, at least at page 8, paragraph 0047.

In summary, it is submitted that claims 12-26, 31 and 32 as amended have traversed and overcome all of the rejections set forth by the Examiner, and are now in a

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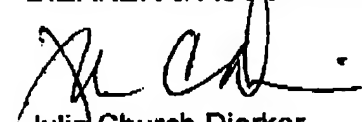
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condition suitable for allowance. Should the Examiner believe otherwise, it is submitted that the claims as amended qualify for entry as placing the application in better form for appeal.

Further and favorable consideration is requested. If the Examiner believes it would expedite prosecution of the instant application, he is cordially invited to contact Applicant's attorney at the below listed number.

Respectfully submitted,

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